

BASF Corporation

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January 11, 2002

Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention & Toxic Substances, 7407
1200 Pennsylvania Avenue, NW
Washington, DC 20460

COMPANY SANITIZED

8EHQ-00-14692
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Ladies and Gentlemen:

Subject: Supplementary Information to EPA Document Number 8EHQ-00-14692. Final results of a chronic toxicity and carcinogenicity study in Wistar rats with an experimental fungicide

In a previous submission, BASF Corporation reported gross pathological changes in the duodenum of rats in a chronic toxicity study with the experimental fungicide Substituted Oximether. The test substance was administered to groups of 70 male and 70 female Wistar rats at dietary concentrations of 0, 100, 500 and 2,500 ppm. All groups were treated for 24 months. The study was carried out in accordance with the following test guidelines: 87/302 EEC and OECD 453.

Summary of Relevant Results:

In an earlier submission, gross pathological changes in the duodenum were reported. In this submission, oncogenic changes observed in the duodenum, and thyroid, are presented:

Incidence duodenum neoplasia

Sex	Male				Female			
Dose level (ppm)	0	100	500	2,500	0	100	500	2,500
No. of animals /group	70	70	70	70	70	70	70	70
Adenoma	0	0	0	0	0	0	0	1
Adenocarcinoma	0	0	0	2	0	0	0	0

Incidence thyroid gland follicular cell neoplasia

Sex	Male				Female			
Dose level (ppm)	0	100	500	2,500	0	100	500	2,500
No. of animals /group	70	70	70	70	70	70	70	70
Adenoma	3	3	3	10	0	1	1	2
Adenocarcinoma	0	2	0	1	0	0	1	1

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Although these findings occurred only at high dose levels, which are far above any expected human exposure, BASF Corporation understands that the reporting of the study results is in accordance of EPA's policy. Please note that a sanitized version of this letter is enclosed, treating the chemical identity as confidential business information. The confidential chemical name is referred to as "Substituted Oximether". An up-to-date confidentiality substantiation letter is already on file for this product (8EHQ-00-14692).

Very truly yours,

BASF CORPORATION



Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

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Enc.